# CRC Clinical Trials Management System (CTMS): An Integrated Information Management Solution for Collaborative Clinical Research

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*Abstract: The Chronic Lymphocytic Leukemia (CLL) Research Consortium (CRC) consists of 9 geographically distributed sites conducting a program of research including both basic science and clinical components. To enable the CRC's clinical research efforts, a system providing for real-time collaboration was required. CTMS provides such functionality, and demonstrates that the use of novel data modeling, web-application platforms, and management strategies provides for the deployment of an extensible, cost effective solution in such an environment.*

The CLL Research Consortium (CRC) is a multi-institutional research program funded by the National Cancer Institute (PO1 CA81534) and headquartered at the UCSD Rebecca and John Moores Cancer Center in La Jolla, California. The consortium consists of 8 additional sites including The Burnham Institute (La Jolla, CA), The Dana Farber Cancer Institute (Boston, MA), Johns Hopkins University (Baltimore, MD), Long Island Jewish Medical Center (New Hyde Park, NY), M.D. Anderson Cancer Center (Houston, TX), The Ohio State University Cancer Center (Columbus, OH), Thomas Jefferson University (Philadelphia, PA), and the Mayo Clinic (Rochester, MN). The consortium conducts an integrated program of basic science and clinical research with the objective of determining curative strategies for Chronic Lymphocytic Leukemia. In order to facilitate the clinical component of this research program, an information management solution that provided for real-time collaboration across the consortium's geographically distributed sites was required. To address this requirement, the CRC Clinical Trials Management System (CTMS) was designed by the informatics workgroup of the consortium. This system is currently in use by all member sites of the consortium, and provides the primary medium through which all CRC clinical protocols are conducted. As of the time of submission of this abstract, in excess of 2000 patients are managed via the CTMS system.

The successful design, deployment, and use of the CTMS system was in large part derived from three critical features of the project: the use of novel data modeling approaches, the adoption of effective web application platforms, and the execution of appropriate project management methodologies. Each of these features is described in greater detail in the following sections.

Novel Data Modeling Approaches:
In order to allow for the organic nature of the evolving data sets inherent to the clinical research domain, a flexible data model was needed. Simultaneously, due to the geographically distributed structure of the consortium, the use of web-based user interfaces was of the utmost importance – which in turn dictated the need for a data model that was amenable to such technologies. As a result, a hybrid data model that combines both an EAV (entity-attribute-value) data repository and multiple, relational "data-marts" was utilized. In order to promote the extensibility of the system, a controlled local vocabulary was adopted, which is in turn mapped to the National Institute of Health's UMLS Methathesaurus.

Adoption of Effective Web Application Platforms:
Due to the need to execute the CTMS project in a cost effective manner, while at the same time providing a reasonable level of performance and scalability in the context of web-based interfaces to the CTMS database, an appropriate web application platform and architecture had to be selected. The platform selected incorporates a java-servlet utilizing an XML-based electronic data interchange model, deployed using a RAIC (redundant array of inexpensive computers) architecture.

Appropriate Project Management Methodologies:
Ultimately, the success of the CTMS project was not predicated on the premise of technology or architecture, but rather on the use of appropriate project management. Specific approaches used during the CTMS project included the use of an iterative user interface design model, as well as best-practice derived software engineering and workflow management approaches.

Future directions for the CTMS project include the deployment of comprehensive patient tracking and calendaring features, automated retrospective data quality assurance measures, and increased adoption of XML-based data export functionality.